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ESTIMATION OF GRANISETRON BY RP-HPLC IN ORAL SOLID DOSAGE FORM

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ABSTRACT

A reverse phase high performance liquid chromatographic method was developed for the estimation of granisetron in tablet formulation. The separation was achieved by Luna C_{18} column and orthophosphoric acid buffer pH 7.5 and acetonitrile (70 : 30v/v) as mobile phase, at a flow rate of 1.2 mL/min. Detection was carried out at 305 nm. Retention time of granisetron was found to be 5.007 min. The method has been validated for linearity, accuracy and precision. Linearity was found to be 40-60 µg/mL. The developed method was found to be accurate, precise, selective and rapid for estimation of granisetron in tablet dosage form.

Key words: Granisetron, RP-HPLC.

INTRODUCTION

Granisetron (GRN) is chemically 1-methyl–N–[(3-endo)-9-methyl-9-azabicyclo [3.3.1] non-3-yl]-1H-indazole-3-carboxamide[1] and is used as an antiemetic in chemotherapy induced vomiting. Estimation of granisetron by spectrophotometry has been published by present authors,[2-3] but no method has been reported using RP–HPLC except estimation of the drug in biological fluids[4-6].

EXPERIMENTAL

Instrumentation

Shimadzu UFLC, UV/VIS detector SPD 20A, LC 20AT pump system. The chromatographic column used was a reverse phase Phenomenex Gemini C_{18} column (250 x 4.60 mm, particle size 5 µ).

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Chromatographic conditions

The mobile phase consists of mixture of orthophosphoric acid buffer pH 7.5 and acetonitrile in the ratio of 70 : 30 v/v and was filtered through 0.45 µ membrane filter and sonicated before use. The flow rate of mobile phase was maintained at 1.2 mL/min. The temperature was ambient and the volume of injection was 20 µL. The eluent was monitored at 305 nm.

Preparation of mobile phase

Preparation of buffer

A quantity of 1.5 mL of ortho-phosphoric acid was made up to 800 mL with water. The pH was adjusted to 7.5 by using triethylamine and the solution was filtered by using vacuum filter.

Preparation of mobile phase

The mobile phase was prepared by mixing the buffer and acetonitrile in the ratio 70 : 30. It was filtered through membrane filter applying vacuum.

Preparation of standard stock solution

The standard solution was prepared by dissolving 50 mg of drug in mobile phase and made up to 100 mL in a volumetric flask with the mobile phase.

Preparation of sample solution

Twenty tablets were accurately weighed and powdered. The powder equivalent to 10 mg was accurately weighed and transferred into a 100 mL volumetric flask. The contents were dissolved in 25 mL of the mobile phase and sonicated for 15 min. Then the solution was made up to the volume with the mobile phase. The resulting solution was filtered through a nylon membrane filter and the first 5 mL of the filtrate was discarded.

Assay procedure

20 µL of the standard stock solution was injected for all concentrations and the retention time was determined. The peak area versus concentration was plotted as calibration graph. The sample solution was also analyzed by injecting 20 µL of the solution and the peak area was determined. The amount of GRN present in commercial tablets was calculated by comparing the peak area of standard and sample.

RESULTS AND DISCUSSION

In this method, C_{18} column and reverse mode were used for analysis. The mobile phase was orthophosphoric acid buffer pH 7.5 : acetonitrile in the ratio 70 : 30 at a flow rate of 1.2 mL/min. The effluent was monitored at 305 nm and the retention time was found to be 5.007. A calibration graph was constructed using peak area versus concentration. The LOD and LOQ were found to be 1.8266 and 5.5352 µg/mL. The % RSD was less than 1, which showed the reproducibility of method. The system suitability parameters[7] are shown in table 1. The results of analysis and recovery studies are shown in Table 2.

Table 1: System suitability parameters

Parameters	Results obtained
No. of theoretical plates	10,469
Linearity in µg/mL	40-60
Accuracy (% recovery)	98.73
LOD (µg/mL)	1.8266
LOQ (µg/mL)	5.5352
Capacity factor	4.37
Asymmetry factor	1.28
Correlation coefficient	0.9996
Slope (m)	38.6101
Intercept	9.7161

Table 2: Assay and recovery studies

Tablet	Label claim (mg)	Amount found by proposed method (mg)*	% Label claim	Recovery studies		
				Amount of drug added(mg)	Amount of drug recovered (mg)	% recovery
GRN	1.000	0.9882	98.82	0.5	0.4936	98.73

*mean of three readings

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